

**Drug Utilization Review Board  
Meeting Minutes, Open Session  
May 13, 2009**

<b>Drug Utilization Review Board</b> Meeting Minutes, Open Session EDS / Forbes Field Capital / Cedar Crest Room Topeka, KS May 13, 2009	<b>Members Present:</b> Michael Burke, M.D., Ph.D., Chair Dennis Grauer, Ph.D. Judy McDaniel Dowd, PA-C Brenda Schewe, M.D. Daniel Sutherland, R.Ph. Kevin Waite, Pharm.D. <b>KHPA Staff Present:</b> LeAnn Bell, Pharm.D. Aimee Grubb, Recorder Shelly Liby Margaret Smith, M.D., M.P.H., M.H.S.A <b>EDS Staff Present:</b> Karen Kluczykowski, R.Ph. Deb Quintanilla, R.N. Lisa Todd, R.Ph. <b>HID Staff Present</b> Candace Rieth, Pharm.D.	<b>Representatives:</b> Mike LaFond, Abbott Cyndee Davies, AstraZeneca Mark Weisz, BMS Don Larsen, Forest Patty Laster, Genetech Ann Gustafson, GlaxoSmithKline Susan Zalenski, Johnson & Johnson Matt Stafford, Merck Lon Lowvy, Novartis William Voegtli, Novartis Jim Baumann, Pfizer Phil King, Pfizer
TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Burke, Chair called the meeting to order at 10:05 a.m.	
II. Announcements	Ms. Todd asked the public to fill out the conflict of interest forms if they wanted to speak to the board. There is a limit of five minutes per drug.	
III. Old Business  A. Review and Approval of March 11, 2009 Meeting Minutes          B. Change to Serevent <sup>®</sup> and Foradil <sup>®</sup> PA Criteria	Dr. Burke noted that the word concurrently was added to the PA criteria for Serevent <sup>®</sup> and Foradil <sup>®</sup> on page 16 of the minutes. It now states, “patient must be concurrently using an inhaled corticosteroid with Serevent <sup>®</sup> or Foradil <sup>®</sup> .” The wording change was to capture the intent of the Board’s PA decision.  Dr. Burke asked for a motion to accept the minutes.  Dr. Burke referred to the changes in the Serevent <sup>®</sup> and Foradil <sup>®</sup> PAs. He asked for a motion to accept the change to the PAs which is the inclusion of the word concurrently.	Ms. Dowd moved that we accept the minutes.  Mr. Sutherland seconded the motion and it carried with a unanimous vote.  Mr. Sutherland moved to accept the change to both the Serevent <sup>®</sup> and Foradil <sup>®</sup> PA criteria.  Dr. Schewe seconded the motion and it carried with a unanimous vote.



	<p>on PA. For example Retin-A<sup>®</sup> had a 90% approval and savings of \$5,000. Is that worth it? Ms. Quintanilla said Retin-A<sup>®</sup> is now on AutoPA; therefore, Dr. Burke agreed it doesn't cost anything. Mr. Sutherland asked if it goes through the initial paper PA. Ms. Quintanilla said that the system looks back into the claims history 15 months to find a physician claim with the diagnosis code that is required for it, and if it does then a paper PA is not needed.</p> <p>Dr. Burke asked if there were any other items that the board was interested in discussing. Ms. Quintanilla pointed out the PPI dosage limitation. She said that there is a Super PA to allow the two doses. Dr. Waite asked if a lot of those are duplicate patients. Ms. Quintanilla said since the PAs are good for six months some of the PAs are done twice per year. Dr. Burke asked if there is any negative feedback from either the prescriber or consumer when their PA is denied. Ms. Quintanilla pointed out that there were 22 appeals out of 446 that were denied. Dr. Bell said we do occasionally receive negative letters, but we aren't being flooded with them.</p> <p>Dr. Waite asked if there is any reason to keep Rifampin<sup>®</sup> on PA. Ms. Quintanilla said there was an increase in PAs from 2007. Ms. Todd said that it has been moved to AutoPA.</p> <p>Dr. Burke stated that we cover Suboxone<sup>®</sup>, but methodone is not covered for maintenance, but the Suboxone<sup>®</sup> would be the equivalent for methodone maintenance so there is an inconsistency. Ms. Quintanilla said there is very strict criteria for Suboxone<sup>®</sup>. The provider has to be approved by SAMSHA in order to prescribe it. Ms. Todd added regardless of Medicaid a retail pharmacist can't dispense methadone for maintenance on any insurance plan because it is against pharmacy law.</p> <p>Mr. Sutherland asked which drugs in the report were not on AutoPA. Ms. Quintanilla said there are only 11 of these drugs that are on AutoPA. Mr. Sutherland asked if they will all be on AutoPA in the future. Ms. Quintanilla said we are working toward putting them all on AutoPA. Dr. Bell said some will never be on AutoPA, such as growth hormones, because they require too much clinical data. She also mentioned that there are some enhancements being made to the AutoPA system. These include allowing the diagnosis to be pulled off the pharmacy claim and screening of Healthcare Common Procedure Coding System (HCPCS) codes.</p> <p>Ms. Quintanilla presented the spreadsheet for the PDL drugs. The PPIs have decreased in PAs processed from 992 in 2007 to 762 in 2008. The PPIs are on AutoPA now.</p>	
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C. Health Information Design (HID)  
Retrospective Drug Review - DUR  
Topic Selection of Interventions

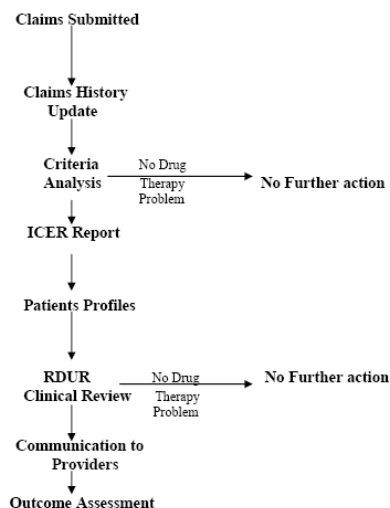
Dr. Grauer asked if the number of lives covered is roughly the same between 2007 and 2008. Ms. Quintanilla said they are pretty close. Dr. Grauer noted that there is a significant reduction in the PDL requests. Ms. Quintanilla said that for 2007 there were a total of 2,886 requests for the PDL drugs and in 2008 there were a total of 2,451. Costs in 2008 were higher because the cost of several drugs went up.

Dr. Bell updated the board on AutoPA since it wasn't captured in the report. There were 223 PDL PA requests in March. 182 of those were approved and 90 of those 182 approvals were approved by AutoPA. There were 184 requests clinical PAs. 130 of those were approved, 13 of which were approved on AutoPA. This number is low because there are only 11 drugs on clinical PA now.

Dr. Burke asked for further discussion from the board. There was none.

**Health Information Design (HID) Retrospective Drug Review - DUR  
Topic Selection of Interventions**

Candace Rieth, HID, gave a brief overview of the Retrospective Drug Utilization Review process. Page three of the handout shows the step process, shown below, that HID goes through when sending the letters.



She then presented a sample patient profile. The patient ID, date of birth, gender, and the number of pharmacies and prescribers the patient has seen are included. In the example shown, even though NSAID therapy is being

Dr. Schewe moved to select narcotics, asthma, and COX-II/NSAIDS for the DUR intervention topics. The topics need to be reviewed by June 30 for Fiscal Year 2009.

Dr. Grauer seconded the motion and it carried with a unanimous vote.

	<p>reviewed all of the criteria exceptions, up to six, will print out on the patient. There may be unrelated criteria being reviewed, but all of the exceptions will show on the profile.</p> <p>Next the case summary information was listed. This information alerts the reviewer that a letter was sent and when it was sent so there isn't a duplicate letter going within six months of the previous letter.</p> <p>Also included is the patient's drug history from the past year. ICD-9 diagnosis codes are listed at the back of the profile. The providers are listed as well, so that if there are duplicate medications the reviewer can check to see if the same prescriber wrote both of the prescriptions.</p> <p>A sample prescriber letter was presented. The actual letter contains an alert message that tells the prescriber why the letter is being sent. The second page is a prescriber response. The prescriber can fill this out and return it with comments and questions. This feedback can then be used to get perform a program assessment. Most letters that are sent will have only the first two pages, but there are some cases where a third page is sent giving background information on the topic. The letter will include the specific prescriptions that are attributed to the established criteria. The letters may go to multiple physicians if it is noted on the profile that there are multiple physicians prescribing. A physician will not receive more than one letter on a patient, so if a patient hits more than one criteria there will still only be one letter, but with all the information for the different criteria.</p> <p>Dr. Burke commented that he liked the prescriber response. Dr. Rieth said that this is important especially if it is a patient that is not under the provider's care because research can then be done to see if the pharmacy is billing with incorrect provider IDs and get more information. Dr. Grauer asked what kind of response is received from the providers. Dr. Rieth said at the start of the program the response rate is higher because there may be some fear of punitive damages. As time goes by the response rate will decrease. On average, the response rate is between 20-60%. Mr. Sutherland asked how many letters are sent for the same issue. Dr. Rieth said there is no limit. If it is a specific issue a letter may be sent once and then not again for six months to a year. A letter may be sent again on that same patient for a different issue. Dr. Bell asked if the Patient Diagnosis/Prescription History Profile is sent to the physician. Dr. Rieth said that the profile is for the reviewer only. A lot of the information is included in the letter as far as what medicines the criteria is hitting on, other physicians, etc. Dr. Schewe asked if the letter is just sent with the provider number or if the provider's name is put on it as well. Dr.</p>	
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	<p>Rieth said every state does it differently, but most states just use the provider number. Dr. Schewe prefers putting the provider name on the letters.</p> <p>Dr. Rieth presented the following five intervention topics: asthma, sedative hypnotics, narcotics, COX-II/NSAIDs, and muscle relaxants for selection to complete the 2009 fiscal year. Utilization data, for all five classes, were provided. Dr. Rieth included excerpts from the criteria that could be used to review under the main topic. She stated that criteria can be built to focus on the groups that the Board chooses.</p> <p>To help choose the topics Ms. Todd referred the Board to the history of interventions that the Board chose in the past. Dr. Rieth went over the indicators for each of the five criteria for the intervention topics.</p> <p><i>Asthma</i></p> <p>Dr. Burke indicated that the board has recently reviewed the topic of long-acting beta agonists combined with inhaled corticosteroids, so this would support that.</p> <p><i>Sedative-Hypnotics</i></p> <p>Ms. Todd thought this topic was interesting because PAs were required for some of the benzodiazepines, but then the coverage was opened up to encourage use of benzodiazepines instead of the more expensive sedative-hypnotics. When looking at claims it seems that many beneficiaries take both benzos and sedative-hypnotics.</p> <p>Dr. Waite said that when looking at the costs of sedative-hypnotics about 20% can be eliminated because Diastat AcuDial™ is a rectal gel for seizure treatment.</p> <p>Dr. Burke stated that some of the quality indicators are going to pull some huge numbers because of the concurrent use of an antidepressant with a sedative-hypnotic. It is a common practice that if a patient is on an antidepressant and is having insomnia a sedative-hypnotic will be added to their treatment. Dr. Rieth said at that point it goes to be reviewed. There are total risk scores on the profile that the reviewer would look at. Dr. Burke asked if Dr. Rieth would come back and show slides on opportunities after the Board chooses these topics. Dr. Schewe said there isn't enough time to get that done before the end of the fiscal year. Dr. Rieth said the ICER report will show how many people hit against each indicator. Dr. Burke asked if there is a limit to the number of letters that can be sent out. Dr. Rieth said there is no limit. Dr. Bell asked if we can pick and choose the criteria. Dr. Rieth said</p>	
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	<p>that can be done, but the list shown is a sample list and there are many more criteria for each intervention. Dr. Burke clarified that the criteria will be run against the database. It will pull out the beneficiaries that hit against those criteria. Those beneficiaries will be prioritized into low, medium, and high risk. Then letters will be sent for beneficiaries with high risk? Dr. Rieth said a pharmacist reviewer goes over every single profile to make sure it is worthwhile. Dr. Burke asked who the reviewer is. Dr. Rieth said it would be an HID person.</p> <p><i>Narcotics</i></p> <p>Dr. Grauer stated narcotics have never been reviewed.</p> <p>Dr. Schewe said it would be good to review short-acting narcotics. Dr. Bell confirmed that PRN chronic use of short-acting is one of the criteria HID has. Dr. Rieth said it is a good topic to review because there are multiple physicians. Dr. Schewe said that she wants to know all the other providers and pharmacies that the beneficiaries are using. Dr. Grauer stated that there is a clear perception that nothing is being done. Dr. Rieth asked about the Prescription Drug Monitoring Program (PDMP). Dr. Bell stated that a funding grant was submitted but it didn't get approved. Dr. Burke asked if PERC is sending out any letters. Dr. Smith said they are not. Dr. Rieth said other states with PDMP have software that gives physicians access to patient's history and whether it is paid with cash, third party, etc.</p> <p><i>COX-II/NSAIDs</i></p> <p>Dr. Burke asked about the use of COX-II. Dr. Rieth stated that COX-II make up the majority of the NSAID usage for the month of January. Dr. Waite said the timing for this intervention is good because of the recent recommendation that the elderly should not be on NSAIDS; they should go from acetaminophen to opiates. Dr. Grauer asked if there is a criterion for elderly patients. Dr. Rieth said there is an elderly criterion. Dr. Bell asked if specific criteria can be built. Dr. Rieth said as long as there is some sort of reference then it can be built.</p> <p><i>Muscle Relaxants</i></p> <p>Dr. Grauer stated because of the overlap between muscle relaxants and narcotics we may not want to review them at the same time.</p> <p><i>Topic Selection</i></p>	
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<p>D. Marinol®</p> <ul style="list-style-type: none"> <li>i. Follow-Up to Letters</li> <li>ii. New PA Criteria</li> <li>iii. *Public Comment</li> <li>iv. Board Discussion/Action</li> </ul>	<p>Dr. Burke said asthma could dove tail with the new PA criteria for long-acting beta agonists and steroids. The COX-II/NSAIDs could be a good topic if a reference was found in regard to avoiding use in the elderly. Narcotics is always an interesting topic.</p> <p>Dr. Burke asked each board member what topics they would like to see reviewed.</p> <ul style="list-style-type: none"> <li>• Dr. Waite and Ms. Dowd: asthma, narcotics, and COX-IIs/NSAIDs</li> <li>• Dr. Grauer: asthma, narcotics, sedative/hypnotics</li> <li>• Mr. Sutherland: asthma, narcotics, sedative/hypnotics</li> <li>• Dr. Schewe: narcotics, sedative/hypnotics</li> </ul> <p>Dr. Burke asked the state for input. Dr. Bell said narcotics were most interesting to her.</p> <p>Dr. Burke asked for a motion.</p> <p>Dr. Bell asked if the Board will be able to choose the specific criteria that they will hit up against. Dr. Burke requested an electronic version of the quality indicators. Dr. Bell said that it may not be too late to change them. She also said that ACS used to auto-generate letters and there were no reviewers.</p> <p>Dr. Burke said that the Board will need to be informed of what the quality indicators are because they will be receiving feedback on the letters from their colleagues. He also questioned the letterhead that would be used and who would sign the letters. Ms. Todd said that in the past they have used KHPA letterhead. Dr. Rieth said typically the Board Chair and Pharmacy Program Manager signs the letters, but it could be signed by the Board as a whole. Ms. Todd said that in the past the signature was Kansas DUR Board.</p> <p><b><u>Marinol®</u></b></p> <p>Dr. Bell said that letters were sent out to high prescribers around mid-April. It stated that clinical trials had shown that doses over 7mg/kg, about 20 mg for an average size person, were not shown to be effective. There were about 50 beneficiaries and 8 prescribers involved. There hasn't been enough time to see a significant impact on claims since letters went out in mid-April. There are a couple of prescriptions that came in for May that were for 20mg that had previously been at a higher dose. She mentioned that there are some beneficiaries that are on a higher dose with 5mg which is more expensive, so</p>	<p>Dr. Schewe moved to accept the Marinol® PA criteria without the bullet requiring a specific BMI.</p> <p>Dr. Grauer seconded and it carried with a unanimous vote.</p>
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	<p>an option would be to look at a dose optimization program to switch them over to at least 10mg. No public comment.</p> <p>Dr. Bell spoke with Dr. Sweet about the BMI of 27 being a little high. Her thoughts were that she could probably go with 24, but anything less than that would be too low primarily because BMIs are pretty skewed on height and weight.</p> <p>Dr. Burke referred the Board to the PA criteria for Marinol<sup>®</sup>.</p> <p><b>Criteria for dronabinol (Marinol) above daily dose of 20mg:</b></p> <p>Must meet all of the following:</p> <ul style="list-style-type: none"> <li>• Must have intractable nausea</li> <li>• Must have BMI of 24 or less</li> <li>• Prescribed by a oncologist or HIV specialist</li> <li>• Doses of 20mg/day trialed and found ineffective for nausea control</li> </ul> <p>Doses of greater than 30mg/day will not be approved.</p> <p>Dr. Schewe said that there is no data behind the BMI of 24 or less. She said Marinol<sup>®</sup> is used for two different things: increased appetite for people who are losing weight and intractable nausea. BMI is not important when using Marinol<sup>®</sup> for intractable nausea. But the question is will it be covered for AIDS or cancer patients who are getting Marinol<sup>®</sup> for appetite stimulation. Dr. Burke said for 20mg or less per day PA is not required. The clinical trial results didn't show additional benefit above the 20mg per day dose. Dr. Schewe said there are two different issues at hand. For intractable nausea the BMI doesn't matter; for appetite stimulation BMI does matter, but 24 is way too high because a normal BMI 19-22. Unless a patient went from a BMI of 30 to a BMI of 20 that's a different issue not just a number. Ms. Dowd said the PA could say and/or must have a BMI of 24. Dr. Schewe asked if we are covering it for appetite stimulation. Dr. Bell said there are no restrictions on it right now so it is covered for everything. Dr. Grauer clarified that for appetite stimulation the maximum daily dose is 20mg. Dr. Burke said the studies were done using mg/meter<sup>2</sup>. Dr. Schewe proposed that anything over 20mg be covered only for intractable nausea, so take the BMI bullet off the PA criteria.</p>	
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<p>E. Aromatase Inhibitors: Femara<sup>®</sup>, Arimidex<sup>®</sup>, Aromasin<sup>®</sup> - Age and Gender Restrictions</p> <p>i. *Public Comment</p> <p>ii. Board Discussion/Action</p>	<p><b><u>Aromatase Inhibitors: Femara<sup>®</sup>, Arimidex<sup>®</sup>, Aromasin<sup>®</sup></u></b></p> <p>Dr. Bell said the aromatase inhibitors are being used off label for treatment of fertility in women and sometimes in men. CMS specifies we don't cover anything for infertility treatment. In the last fiscal year 21 people under the age of 45 had received these products..</p> <p>Phil King, Pfizer, said he has not seen the proposed criteria. Dr. Bell said there isn't any at this time. Mr. King said Aromasin<sup>®</sup> is usually used no more than five days, so putting a quantity limit on the drug may be easier to manage than the indications. Aromasin<sup>®</sup> has not been proven to promote fertility. Dr. Schewe asked Mr. King if he would have a problem with restricting it to female use only. He said from a label standpoint yes. The cancer society recommends this treatment for males who develop breast cancer. Dr. Schewe said that in those cases a PA could be required, but if the patient didn't have male breast cancer that would cut them all off. Dr. Bell asked if there is a way to put a minimum quantity limit on the drug in the claims system. Ms. Kluczykowski said there are minimum and maximum restrictions allowed. Dr. Grauer asked if there could be a hard edit for a diagnosis of cancer. Mr. King said that Aromasin<sup>®</sup> is indicated after tamoxifen use for 2-3 years. So there would definitely be a cancer indication. William Voegtli, Novartis, asked that there not be an age restriction placed on Femara<sup>®</sup></p> <p>Dr. Burke stated that the aromatase inhibitors are approved for the treatment of breast cancer. What has been reported in the literature is the possibility that the drugs may increase fertility in males, that they may benefit in increasing the onset of puberty in males with delayed puberty, and increase fertility in females by increasing ovulation. These considerations are all still at an experimental stage. The Board's position is that we don't police the use of drugs by indication, but we don't promote off label use. Dr. Bell said we have an age panel in AutoPA that could be used. Dr. Grauer asked if a diagnosis of cancer and post-menopausal could be used as the criteria. Dr. Schewe said you can't tell that they are post-menopausal. Dr. Burke suggested a diagnosis of breast cancer. Dr. Bell said the benefit of setting a minimum age is for those people have just become eligible for Medicaid we wouldn't have history on them. Dr. Grauer said you can't really set a post-menopausal age. Dr. Burke said without the claims data the PA Unit would need to talk to the physician who would give the diagnosis of breast cancer.</p> <p>Dr. Burke asked for a motion.</p>	<p>Dr. Grauer moved to put Aromatase Inhibitors on AutoPA that specifies the diagnosis of breast cancer.</p> <p>Dr. Schewe seconded and it carried with a unanimous vote.</p>
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